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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,677	08/24/2001	Robert H. Harris	13095	2566

7590 01/06/2004

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,677	HARRIS, ROBERT H.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/20/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,51,56 and 58-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☒ Claim(s) *2-19, 51, 56, 58-62* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Pursuant to preliminary amendment (10/20/03), claims 1, 7, 9, 15, 51, 56, 58-62 have been amended, and claims 20-50, 52-55, 57, 63-72 cancelled. Claims 1-19, 51, 56, 58-62 remain pending.

Applicants' election of Group 4 with traverse is acknowledged (claims 1-19, 51, 55, 58, limited to G4). Also acknowledged is the elected specie.

Applicants have asserted that the inventions are not independent and distinct. At the same time, however, there is no admission that the groups identied by the examiner are obvious over the others. For example, applicants could make an admission that the references identified below anticipate, or render obvious, each of the various groups. The absence of such an admission indicates that applicants recognize the distinctness of the various groups. As for double patenting, in the event that such a rejection is imposed, applicants may traverse such a rejection as deemed appropriate. Applicants have also argued that requiring filing of divisional applications imposes an undue financial burden on applicants. At the same time, however, applicants may not recognize the examining costs of searching for, and rejecting over, dozens of references. Given what is encompassed by the terms "electron donating" and "electron withdrawing", the claimed genus is of infinite size, and as matters currently stand, there are hundreds of §102(b) references that could be legitimately applied against claim 1. However, in the event that significant limitations are introduced into the claims, the restriction requirement may be reconsidered.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Yoshino (USP 4,707,468).

Yoshino discloses (cols 5-12) various analgesic peptides. Consider, for example, the first of these, which is the following:

Me-Tyr-Gly-Gly-Phe-Leu-Arg-Arg-NH_2

In the instant application, the claimed peptides are presented in the C → N direction, rather than the conventional N → C direction. For the case of "n" being an integer of 3 and R_2 representing hydrogen, claim 1 is drawn to a method of using a peptide of the following formula to alleviate pain:

R_1-CO-NH-CH(R_3)CO-NH-CH(R_3)CO-NH-CH(R_3)CO-NHR

The disclosed peptide is encompassed by claim 1 when the substituent variables correspond as follows ("X" is a variable created by the examiner):

R_1 = phenylethyl that is substituted once with methylamino (*alpha-* to the carbonyl group) and once (on the phenyl ring) with hydroxyl;

R_{3a} = hydrogen;

R_{3b} = hydrogen;

R_{3c} = benzyl;

R = 1-(3-methylbutane) that is substited at the "1" position with "X", wherein "X" is an electron-withdrawing group, more specifically the following: -CO-Arg-Arg-NH_2

Thus, the claim is anticipated.

*

Claim 1 is rejected under 35 U.S.C. §102(a) as being anticipated by Bialer (WO 99/43309).

Bialer discloses (e.g., page 35, claim 16) that N-acetyl N-benzylglycinamide can be used to treat pain.

The claim is anticipated when "n" is 1, R_1 is methyl, and R is benzyl.

The reference Fu (*J Pharmacol Exp Ther*, 2000) was stricken from the IDS because only an abstract was provided.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600